K091268

SEP 18 2009

1 510(k) SUMMARY

1. **Submitted by:**

Hospira, Inc.
D-389 Bldg. H2
275 N. Field Drive
Lake Forest, IL 60045

Phone: (224)212-5316
Fax: (224) 212-5401

Contact: Daniela Weksler

2. **Manufacturer and Establishment Registration Number:**

Manufacturer:

ICU Medical (UTAH), Inc.
4455 Atherton Dr.
Salt Lake City, UT 84123

Establishment Registration #: 1713468

3. **Date Prepared:** April 24, 2009

4. **Name/Classification of Device:** Class II
74 DYG – 21 CFR 870.1240 - Flow-Directed Catheter
74 KRB – 21 CFR 870.1915 – Thermodilution Probe
74 DQE – 21 CFR 870.1230 – Fiberoptic Oximeter Catheter

5. **Trade Name of Proposed Device:** Hospira Critical Care and Advanced Sensor Catheter

6. **Predicate Devices:** Hospira Critical Care and Advanced Sensor Catheter (K061450)

7. **Proposed Device Description:**

The Hospira Critical Care and Advanced Sensor Catheters have multi-lumens that incorporate some or all of the following components and features: a distal balloon for positioning the catheter tip via blood flow within the pulmonary artery, a heater coil for determining continuous cardiac output, a thermistor for monitoring core temperature and cardiac output, fiber optics for monitoring mixed venous oxygen saturation (SvO_2), and access ports for drug delivery or blood sampling. In addition, the Hospira Critical Care Pacing Lead Catheters include an access port for use with Transluminal Right Ventricular Pacing Leads. The catheters also incorporate insertion distance markings and are provided with a syringe for inflating the balloon.

8. Statement of Intended Use:

Hospira Advanced Sensor Catheters:

Indicated for the assessment of the hemodynamic status of a patient, including but not restricted to the following: Venous Pressures, Cardiac Output, Oxyhemoglobin Saturation, and Venous Blood Sampling. A secondary indication is for the therapeutic infusion of solutions.

Hospira Critical Care Catheters:

Indicated for the assessment of hemodynamic status through right atrial, right ventricular, and pulmonary artery and/or wedge pressure monitoring for patients including the following : acute heart failure; differentiating ruptured ventricular septum form mitral regurgitation; diagnosis of tamponate; severe hypovolemia; complex circulatory situations (e.g., fluid management with acute burn patients); medical emergencies; adult respiratory distress syndrome; gram negative sepsis; drug intoxication; acute renal failure; hemorrhagic pancreatitis; intra- and postoperative management of high risk patients; history of pulmonary or cardiac disease; fluid shifts (such as extensive intra-abdominal operations); management of high risk obstetrical patients; known cardiac disease; toxemia; premature separation of the placenta; cardiac output determination by thermodilution method; and blood sampling.

Additional indication for Hospira Critical Care Pacing Lead Catheters:

Indicated for temporary transluminal ventricular pacing using a temporary ventricular lead.

9. Summary of Substantial Equivalence

The Hospira Critical Care and Advanced Sensor Catheters as described in this submission are substantially equivalent to the predicate Hospira Critical Care and Advanced Sensor Catheters (K061450) with respect to manufacturing methods and materials with respect to the following characteristics:

Similarities:

1) The catheters have the same intended use and indications for use.
2) The catheters contain the same type of components.
3) The method of sterilization is the same.
4) The manufacturing process is the same.
5) The resin blend used for the balloon is the same.
6) The resin used for the bump and extrusion tubing of the Advanced Sensor Catheters is the same.

Differences:

1) The material used to manufacture the balloon in both the Critical Care and Advance Sensor Catheters will be a slightly different formulation.
2) The resin dye and stiffness specification for the extrusion used in the Advance Sensor Catheters.
3) The bond coat insulation on the heater lead wire for the Advance Sensor Catheters

10. Statement of Safety and Effectiveness

The Hospira Critical Care and Advanced Sensor Catheters have been tested for biocompatibility and for expansion symmetry, over inflation, multiple inflations, deflation time, and burst strength and have passed all of the acceptance criteria. The Hospira Critical Care and Advanced Sensor Catheters meet the functional claims and intended use as described in the product labeling, and are as safe and effective in terms of substantial equivalence as the predicate catheters described in this document.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

SEP 18 2009

Hospira, Inc.
c/o Mr. Keith R. Dunn
Manager, Global Regulatory Affairs
275 N. Field Dr.
Lake Forest, IL 60045

Re: K091268
Trade/Device Name: Hospira Critical Care and Advanced Sensor Catheters (see enclosure for listing of 29 models)
Regulatory Number: 21 CFR 870.1230
Regulation Name: Fiberoptic Oximeter Catheter
Regulatory Class: Class II (Two)
Product Code: DQE, DYG and KRB
Dated: August 17, 2009
Received: August 18, 2009

Dear Mr. Dunn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

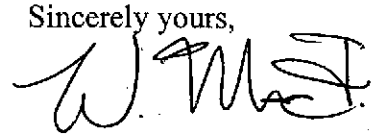
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosures

Indications for Use

510(k) Number: K091268

Device Name: **Hospira Critical Care and Advanced Sensor Catheters**

Indications for Use:

Hospira Advanced Sensor Catheters:

Indicated for the assessment of the hemodynamic status of a patient, including but not restricted to the following: Venous Pressures, Cardiac Output, Oxyhemoglobin Saturation, and Venous Blood Sampling. A secondary indication is for the therapeutic infusion of solutions.

Hospira Critical Care Catheters:

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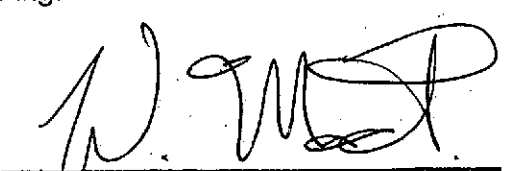

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K091268

Additional indication for Hospira Critical Care Pacing Lead Catheters:

Indicated for temporary transluminal ventricular pacing using a temporary ventricular lead.

Prescription Use __X__ **AND/OR** **Over-The-Counter Use**_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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K091268 Hospira Critical Care and Advanced Sensor Cathters (29 models)

Model #	Model Title
412400406	Pentalumen™ Torque-Line® Catheter with Extra Infusion Port
412370406	Pentalumen™ Torque-Line® Catheter with Extra Infusion Port
412390406	Multiflex Torque-Line™ Catheter
412480406	Torque-Line® Catheter
412500406	Torque-Line® Catheter
412510406	Multiflex Torque-Line® S-Tip Catheter
412520406	Pentalumen™ Torque-Line® Catheter with RV Pacing Port
413000402	Pentalumen™ Catheter with RV Pacing Port
412160402	Pentalumen™ Catheter with Extra Infusion Port
412170402	Pentalumen™ Catheter with Extra Infusion Port
412230402	Multiflex Cather
412270402	Multiflex S-Tip Catheter
412290402	Multiflex Cather
412310406	Multiflex Torque-Line™ Catheter
412320402	Pentalumen™ Catheter with Extra Infusion Port
412330406	Pentalumen™ Catheter with Extra Infusion Port
503240406	Opticath ® PA Catheter
503280406	Opticath ® PA Catheter with Extra Port
503370406	Opticath ® PA Catheter with Extra Port
503270406	Opticath ® PA Catheter with Extra Port
503250406	Opticath ® PA Catheter
503440406	Opticath ® PA Catheter with RV Pacing Port
525090413	Opti Q® SvO2/CCO Fiberoptic Catheter (with Q-Tip)
525100413	Opti Q® SvO2/CCO Fiberoptic Catheter (with J-Tip)
525110413	Opti Q® SvO2/CCO Fiberoptic Catheter (with Q-Tip)
525160413	TDQ™ CCO Catheter
525150413	TDQ™ CCO Catheter
503540406	Opticath ® PA Catheter
503550406	Opticath ® PA Catheter